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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,957	12/04/2001	Shoshana Paglin	AP33710 072734.0121	2771
21003	7590	12/28/2004	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,957	Applicant(s) PAGLIN ET AL.	
	Examiner Traviss C McIntosh	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-11,13-21,43,44,46-51 and 53-65 is/are pending in the application.
 4a) Of the above claim(s) 43,44 and 46-51 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3,9-11,15,20,21 and 53-65 is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8,13,14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed October 15, 2004 has been received, entered into the record, and carefully considered. Applicants claim amendments have been entered.

Remarks drawn to rejections of Office Action mailed June 15, 2004 include:

112 1st paragraph new matter rejection: which has been overcome by applicant's amendments and has been withdrawn.

112 1st paragraph enablement rejections: which have been overcome by applicant's amendments and has been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicant's amendments and have been withdrawn.

102(b) rejection which has been maintained in part for reasons of record.

An action on the merits of claims 1-4, 6-11, 13-21, and 53-65 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 4, 6-8, 13-14, and 16-19 under 35 U.S.C. 102(b) as being anticipated by Altan et al. (Document 18 of IDS submitted 2/10/2003) is maintained for reasons of record.

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The claims of the instant application are drawn to the following: claim 1 is drawn to a method of promoting cell death in a cell which has been previously exposed to a chemotherapeutic agent comprising contacting said cell with a plecomacrolide or a benzolaetone enamide which is an inhibitor of vacuolar proton ATPase activity within about 48 of exposure to the chemotherapeutic agent. Claim 13 is drawn to a method for promoting cell death in a cell which has been previously exposed to a chemotherapeutic agent comprising contacting said cell with a plecomacrolide or a benzolaetone enamide which is an inhibitor of acidic vesicular function or acidification within about 48 of exposure to the chemotherapeutic agent. Dependent claims 2 and 14 limit the cells of claims 1 and 13 to cancer cells. Dependent claims 4 and 16 limit the chemotherapeutic agent. Dependent claims 6-8 and 17-19 limit the plecomacrolide.

Altan et al. disclose that administering monensin, bafilomycin A1, or concanamycin to a cell which is resistant to adriamycin from previous therapies, sufficiently changes the cells to that of a drug-sensitive cell thereby rendering the cell vulnerable once again to chemotherapy. Thus, Altan teaches to administer the claimed compounds, which are known in the art to be inhibitors of V-ATPase activity, which is known in the art to promote proton conduction across the vesicle membrane thus inhibit acidification of vesicles, to cells which have been previously treated with a cytotoxic agent (adriamycin, a known chemotherapeutic agent), thereby promoting cell death by once again rendering them vulnerable to chemotherapy (abstract).

Applicant's arguments filed October 15, 2004 have been fully considered but they are not persuasive. Applicants argue that Altan illustrates the disruption of the AVOs that have already formed within the cell and shows that the drug resistant cells are converted to non-drug resistant cells by the redistribution of adriamycin. However, it is noted that if Altan et al., having taken

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the manipulative steps described therein, had attempted to measure for the results as described in the instant application, Altan would have uncovered those results, as they are directly correlative to the method as practiced by Altan. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of using the plecomacrolides and chemotherapeutic agents, as the prior arts method would have inherently performed the method as instantly claimed. Altan teaches to administer the claimed compounds in combination to the same population, and thus would have had the same results. It is noted that applicants amending the claims to "within about 48 hours" is not seen to be overcome the Altan reference. See Ex Parte Novitski, 26 USPQ 2d (BNA) 1389. A hypothetical example clarifies this principle. Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for "a method of making a fire by lighting a flame in the presence of oxygen." Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires. EMI v. Cypress Semiconductor, 2001 US Fed. Cir. Ct. of App. In the instant case, applicant's arguments that Altan does not teach that their compounds inhibited AVO formation is not found to be convincing.

Allowable Subject Matter

Claims 3, 9-11, 15, 20-21, and 53-65 are allowed. The prior art does not teach or fairly suggest the use of a plecomacrolide or benzolactone enamide in inhibiting AVO formation in

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cells which have been previously exposed to irradiation, nor does the prior art teach or fairly suggest the use of a benzolactone enamide in inhibiting AVO formation in cells which have been previously exposed to chemotherapeutic agents.

Additionally, it is noted that the withdrawn claims 43-44 and 46-51 will be further considered upon issuing an allowance to see if rejoinder is indeed required.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

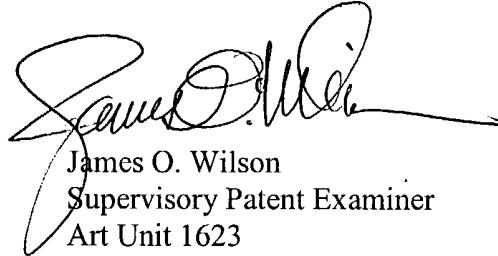
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
December 22, 2004



James O. Wilson
Supervisory Patent Examiner
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